

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

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|---|---|----------------------------------|
| STATE FARM FIRE AND CASUALTY |) | |
| COMPANY, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| V. |) | |
| |) | |
| SPECIALTY SURGERY CENTER, PLLC, |) | |
| KENNETH R. LISTER, M.D., ELIZABETH |) | |
| BRAY, PEGGY B. BUMGARNER, ROGER |) | |
| D. BUMGARNER, WILMA S. CARTER, |) | |
| LAWRENCE CARTER, JUDY COLLINS, |) | |
| WANDA J. COX, PERRY COX, WANDA |) | |
| J. DINGESS, BOBBY A. FOSTER, |) | |
| DOROTHY A. FUELLING, RICHARD E. |) | |
| FUELLING, CRAIG E. WEAVER, |) | Case No. 2:15-cv-00026 |
| Administrator Ad Litem of the Estate of |) | |
| PATRICIA A. GAMBACCINI, DANETTE |) | Chief District Judge Kevin Sharp |
| GRAHAM, GEORGEANNE HUBBARD, |) | |
| LINDA JACKSON, JOHN JOHNSON, EDNA |) | |
| S. KEYES, WILLIAM LAPISKA, SHERRY A. |) | Magistrate Judge Joe Brown |
| MCDAVID, next of kin of DONALD F. |) | |
| MCDAVID, DARWIN L. NEALON, |) | |
| Administrator of the Estate of DALLAS RAY |) | |
| NEALON, JOCELYN KAE NORRIS, JAMES |) | |
| PALMER, MICHELLE PALMER, WANDA |) | |
| L. REED, J.E. REED, JANICE K. RHIND, |) | |
| CHRISTOPHER G. RHIND, SHIRLEY |) | |
| SAVERCOOL, PAULA K. SMITH, JIM F. |) | |
| SMITH, and DALE WILLIS, |) | |
| |) | |
| Defendants. |) | |

**SPECIALTY SURGERY CENTER, PLLC AND KENNETH R. LISTER, MD'S
RESPONSE TO THE INDIVIDUAL TORT VICTIM DEFENDANTS'
MOTION TO STRIKE OR ALTERNATIVELY STAY PROCEEDINGS**

Specialty Surgery Center, PLLC and Kenneth R. Lister, MD (collectively “Tennessee SSC Defendants” or “Defendants”) respond to the *Individual Tort Victim Defendants’ Motion to Strike or Alternatively Stay Proceedings* (hereinafter, at times, the “Motion to Stay”) as follows:

1. Procedural posture and summary of position on this motion

This is a declaratory judgment action brought by the insurer, State Farm Fire and Casualty Company (hereinafter “State Farm” or the “insurer”). The insureds are Specialty Surgery Center, PLLC, and Kenneth R. Lister, MD. State Farm asks the Court to enter a declaratory judgment that State Farm does not have to defend or indemnify the insureds in underlying tort claims. The underlying tort claims are brought by the “Individual Tort Victim Defendants” against the insureds related to the 2012 outbreak of meningitis from contaminated steroid injections. The tort claims are pending as part of multi-district litigation in the U.S. District Court for Massachusetts.

Here, the Individual Tort Victim Defendants (also referred to herein as the “MDL Plaintiffs”) ask this Court to put the declaratory judgment action on hold until the MDL resolves, or at least until the issue of the viability of the MDL Plaintiffs’ product liability claim resolves in the MDL.

The Tennessee SSC Defendants – the insureds under the State Farm policy – do not take a position on whether the Court should grant the instant Motion to Stay.

However, the Motion to Stay presents issues in a way that requires the parties to stake out positions at the intersection of the MDL and the instant coverage action. Thus, the Tennessee SSC Defendants respond below to explain their position on various points directly and indirectly raised in the Motion to Stay.

2. Background

While the factual underpinnings of the MDL complaints against the Tennessee SSC Defendants may not be necessary for the Court to rule on this procedural motion, some context may still benefit the Court.

In 2012, an outbreak of fungal meningitis affected at least 20 states and thousands of people. Hundreds suffered sickness; dozens died. Inevitable litigation followed. The outbreak was traced to three contaminated batches of medication produced by New England Compounding Center, a Massachusetts drug-maker. As the MDL Plaintiffs allege in their MDL Master Complaint, “No one disputes that the contaminated products that caused these horrific injuries were made by [NECC].”¹

NECC’s limited insurance coverage and bankruptcy shifted the MDL Plaintiffs’ focus from NECC to other possible pockets of recovery. The MDL Plaintiffs cast a wide net, suing NECC’s owners, individual NECC employees, the company that constructed the cleanroom where the medications were made, the company that leased the property to NECC, a sister company to NECC, the company that marketed NECC’s products, the company that tested NECC’s medications, and the company that cleaned NECC. The MDL Plaintiffs also sued the health care providers that unknowingly injected the contaminated medication.

In the two dozen cases against SSC, the MDL Plaintiffs sue both SSC (the surgery center where the MDL Plaintiffs were treated with the contaminated medications) and Dr. Lister (the anesthesiologist who unknowingly injected patients with contaminated NECC medication).

¹ MDL Master Complaint, Mass. Dist. Ct. No. 1:13-md-02419-RWZ, Dkt. 545, ¶3.

The MDL Plaintiffs' cases against the Tennessee SSC Defendants essentially ride on two causes of action: (1) negligence² and (2) product liability.³ ⁴ The former alleges that SSC and Dr. Lister negligently purchased medication from NECC, without conducting the appropriate due diligence, and, had they done the proper due diligence, they would not have bought from NECC.⁵ The latter attempts to impose strict liability upon the SSC Defendants, on a theory that they "sold" the defective medication when Dr. Lister injected it into patients.

² Reading the Complaint against the Tennessee SSC Defendants and the media comments by Plaintiffs' attorneys, one may conclude that the Tennessee SSC Defendants bought the contaminated medication on the cheap from a cut-rate, fly-by-night operation, in the hopes of saving a few dollars. That is far from the truth. SSC and Dr. Lister bought the steroid – methylprednisolone acetate, used in epidural steroid injections – because NECC offered a preservative-free version of the medication not available commercially. Dr. Lister preferred a preservative-free version because preservatives were linked to dangerous side effects. Additionally, NECC was not an unregulated, fly-by-night operation. NECC had been inspected by the Massachusetts Board of Pharmacy and by the FDA, and NECC was licensed in Tennessee and in Massachusetts by their boards of pharmacy (and separately by 40+ other states). NECC had state-of-the-art drug-making equipment, certified by independent third parties. And, it openly represented to customers that it followed the gold standard for safety and sterility, "USP 797." There will be factual disputes in the underlying MDL tort claims, of course, but the continued suggestion that SSC purchased medication from NECC solely to save money, and that NECC was some unregulated, unlicensed, *per se* unsafe supplier, does not provide the Court with an accurate factual context.

³ See MDL Master Complaint, Mass. Dist. Ct. No. 1:13-md-02419-RWZ, Dkt. 545; see representative complaint in Middle District case, M.D. Tenn. No. 2:13-cv-00078, Dkt. 1 (*Rhind Complaint*).

⁴ There are other causes of action brought, and various subtleties in the way they are pled, but these are the two primary causes of action against the Tennessee SSC Defendants.

⁵ Additionally, the suggestion that SSC went "rogue" to buy from NECC, to save money and shortcut safety, is not accurate. Media accounts and the Plaintiffs' Complaints gloss over the fact that 3,000 doctor's offices, clinics, ambulatory surgery centers, and hospitals bought from NECC, including dozens of the most respected institutions in the country (e.g., Vanderbilt Medical Group; Emory University; NYU Medical Center; New York Presbyterian-Columbia University Medical Center; Children's Hospital of Los Angeles; Georgetown University Hospital; Boston Children's Hospital; Phoenix Children's Hospital; Children's National Hospital (DC); Children's Healthcare of Atlanta). The customer list is at <http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325467.pdf>. The MDL Plaintiffs' theory is that it was below the standard of practice for a surgery center to buy from NECC. Yet, the customer list shows that ambulatory surgery centers from 19 different states bought from NECC.

3. Explanation of Tennessee SSC Defendants' position on relevant issues

- a. The Tennessee SSC Defendants agree that the legal viability of the product liability claim in the MDL cases is the "key issue" in this coverage action.**

The Tennessee SSC Defendants agree with the MDL Plaintiffs on one issue – the viability of the product liability claim in the underlying MDL cases is likely the central issue in this Court's decision as to whether the State Farm policies offer coverage.

- b. Despite the representations of the "Individual Tort Victim Defendants," Judge Zobel's ruling on the viability of the product liability claim against these health care provider defendants did not unabashedly endorse the legality of the claim, but instead only ruled it clears the low bar⁶ of a motion to dismiss.**

The MDL Plaintiffs' Motion to Stay may leave the impression that the MDL judge provided an iron-clad affirmative endorsement of the Plaintiffs' product liability claims. This is not so. Admittedly, the MDL Court denied the SSC Defendants' Motion to Dismiss the product liability claim. The MDL Court also recognized that there is no Tennessee case law addressing the intersection of product liability and the Tennessee Health Care Liability Act⁷ nor any case law addressing whether health care providers can be sellers under the Product Liability Act⁸. In the absence of any precedent expressly holding a plaintiff cannot sue a health care provider as a seller, the MDL Court decided not to dismiss the claims at the motion to dismiss stage.⁹

⁶ *Flipp v. Town of Rockland*, 613 F.Supp.2d 141, 147 (D. Mass. 2009) (noting the low bar a plaintiff must meet to survive a motion to dismiss).

⁷ No. 1:13-md-02419-RWZ, Dkt. 1360, p. 20 ("The parties offer no case law, and I have uncovered none, addressing these issues with respect to the amended THCLA or to products liability claims specifically.").

⁸ No. 1:13-md-02419-RWZ, Dkt. 1360, p. 28 ("This court's case law research did not unearth any Tennessee cases in which products liability claims were successfully brought against health care providers, nor any cases indicating that health care providers were categorically not sellers or could not be sued under the TPLA.").

⁹ No. 1:13-md-02419-RWZ, Dkt. 1360, p. 30 ("Federal courts hearing diversity matters should be extremely cautious about adopting substantive innovation in state law.") (other cites omitted).

This is not the same as a finding that Tennessee appellate courts have addressed the subject and the claim is valid. It is also not the same as a ruling that SSC and Dr. Lister *are* sellers under the TPLA. Instead, the MDL Court simply found that the claim could continue for the time being given the absence of precedent barring the claim.¹⁰

c. The Tennessee SSC Defendants do not seek an “end run” around an order of the MDL court.

The MDL Plaintiffs suggest that the SSC Defendants are attempting to use this declaratory judgment action to make an “end run” around the MDL Court’s motion to dismiss ruling.¹¹ This is not true. The SSC Defendants did not file the declaratory judgment action. The SSC Defendants did not tell State Farm to file a declaratory judgment action. The SSC Defendants have not filed a dispositive motion on the product liability action in this Court. The SSC Defendants are just that – *defendants* – litigating a case *against them*.

So, the suggestion that the Tennessee SSC Defendants are somehow engaged in procedural manipulation to do an end-run around the MDL Court’s ruling is just not correct. As stated above, the SSC Defendants take no position at this time on whether this Court should address the product liability issue now or later, or issue a stay of the declaratory judgment action.

¹⁰ The Court found at footnote 11 that plaintiffs *cannot* pursue their product liability claim against defendants who did not charge for the drug. [No. 1:13-md-02419-RWZ, Dkt. 1360, p. 31] This would include Dr. Lister.

¹¹ At the last MDL status conference, Plaintiffs’ counsel stated: “It became rather apparent during that status conference that both State Farm, the insurer, and Specialty Surgery Center, one of the defendants, were using that case as a sort of vehicle to try to make an end-run, if you will, around this Court’s previous order related to the ability of plaintiffs to bring claims against Specialty Surgery Center under the Tennessee Products Liability Act and as a result, the individual tort victims who are parties to that case will likely be filing either a motion to strike or a motion to stay that proceeding, pending, essentially, the outcome of those claims in this proceeding.” [Tr., August 5, 2015, Status Hearing, p. 9-10]

- d. Even though it could result in the loss of coverage under the State Farm policies, the Tennessee SSC Defendants' position is that the underlying MDL Plaintiffs cannot maintain a claim for product liability against these health care providers.**

The SSC Defendants are in a unique position. The SSC Defendants wholly and unequivocally assert that the product liability claim is not legally viable under Tennessee law, despite the fact that such a finding in the coverage action could jeopardize coverage under the State Farm policy.

Setting aside the odd posture, the SSC Defendants are confident that, either as a matter of law or as a finding of law applied to the facts, summary dismissal of the product liability claim against the SSC Defendants is the correct finding under Tennessee law. The SSC Defendants are likewise confident in predicting that a Tennessee appellate court would not allow such a claim.¹²

The SSC Defendants will not rehash all their arguments on the viability of the product liability claim here, made over dozens of pages of briefing in the MDL. However, the instant Motion to Stay and the merits of the product liability issue are intertwined in that it is difficult for this Court to decide whether to continue the declaratory judgment action on a path toward a decision on the merits of the product liability issue without, at least generally, understanding the parties' positions. Thus, to contextualize the motion presently before the Court, the SSC Defendants briefly address below why, as a matter of law and on the facts of these cases, product liability is not a viable cause of action.

¹² *Hartford Fire Ins. v. Lawrence, Dykes, Goodenberger*, 740 F.2d 1362, 1364-65 (6th Cir. 1984) ("[a] federal court sitting in diversity is bound to apply the substantive law of the forum state; if the state's highest court has not spoken to the question in controversy, the federal court must discern how the state courts would respond if confronted with the question").

First and foremost, the “new” definition of a “health care liability action” captures the Plaintiffs’ claims, despite their try to recast them as product liability claims:

“Health care liability action’ means *any* civil action...alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, *regardless of the theory of liability on which the action is based.*”¹³

Because the MDL Plaintiffs allege “injury related to the provision of...health care services,” the claims are governed by the HCLA. That necessarily precludes the MDL Plaintiffs from bringing strict product liability actions in direct contravention of the HCLA.

Virtually all law on the subject supports the principle that a health care provider providing a medical service does not “sell” medication used incidental to the treatment so as to be exposed to strict product liability:

1. The Tennessee appellate cases that address the service provider-versus-seller distinction find that providers of professional services are not sellers of items used during the provision of those professional services.^{14 15 16}

¹³ TENN. CODE ANN. § 29-26-101 (emphasis added). Further, this section applies to any health care liability action, “regardless of any other claims, causes of action, or theories of liability alleged in the complaint.” TENN. CODE ANN. § 29-26-101.

¹⁴ See *Delta Refining Co. v. Procon, Inc.*, 552 S.W.2d 387, 389 (Tenn. Ct. App. 1976) (holding contractor was not the seller of a defective pump that he bought from a manufacturer and professionally installed for the plaintiff); *Parker v. Warren*, 503 S.W.2d 938, 945 (Tenn. Ct. App. 1973) (holding carpenters not sellers of the defective lumber used to construct bleachers); see also *Burris v. Hosp. Corp. of Am.*, 773 S.W.2d 932, 935 (Tenn. Ct. App. 1989) (holding claim against a hospital related to use of defective pledges during surgery was governed by Medical Malpractice Review Board and Claims Act, not as a product liability cause of action).

¹⁵ Additionally, Tennessee courts have consistently held that cases related to the administration of medication and adverse reactions are medical malpractice cases, not strict product liability cases. See, e.g., *Sharkey v. O’Toole*, No. M2009-0112-COA-R3-CV, 2010 WL 3293925, at *1-6 (Tenn. Ct. App. 2010) (analyzing case in which physician allegedly prescribed Haldol to a patient with a known allergy as medical malpractice case).

¹⁶ A federal court, in the absence of indication the state’s highest court would find differently, is not free to ignore the rulings of state appellate courts on the issue when deciding a matter of state law. *Central States, SE & SW Areas Pension v. Howell*, 227 F.3d 672, 679, n. 4 (6th Cir. 2000).

2. The RESTATEMENT (THIRD) OF TORTS, which Tennessee's appellate courts turn to when faced with a gap in Tennessee law¹⁷, specifically recommends barring products liability claims against health care providers where the health care provider provides a service, with the defective product used incidental to that service.¹⁸
3. Virtually every state that has addressed the viability of a product liability claim against a health care provider for a defective product used during the provision of health care services has found that the claim cannot be maintained.¹⁹
4. Tennessee courts, considering an analogous question, have found that the Tennessee Consumer Protection Act – the bastion of claims by consumers against merchant sellers for wrongful conduct – does not apply to Tennessee health care providers because they provide a service, not sell a product.²⁰
5. Tennessee's tax law does not treat medical providers like sellers of product for purposes of taxing.²¹

* * * * *

¹⁷ See, e.g., *Jones v. State*, No. M2012-02546-SC-S09-CV, 2013 WL 6795237, *6 (Tenn. 2013) (adopting RESTATEMENT (SECOND) OF TORTS position on immunity from defamation).

¹⁸ The Restatement says:

Courts are unanimous in refusing to categorize commercially-provided services as products for the purposes of strict liability in tort. Thus, strict products liability does not extend to professionally-provided services, such as medical or legal help.

...

Hybrid cases often arise in the medical context, as when a surgeon uses defective forceps during an operation. Most jurisdictions hold that hospitals and doctors provide a service – medical treatment – and immunize them from strict liability for harm from defective products used in medical treatment.

RESTATEMENT (THIRD) OF TORTS § 19, 20.

¹⁹ At last count, 26 of 28 states that had addressed the issue barred the type of claim the Plaintiffs try to put forth. See, e.g., *In re Breast Implant Prod. Liability*, 331 S.C. 540, 544 (S.C. 1998) ("[i]n analyzing this question, we must consider whether the essence of the transaction is the provision of a service or a product. We hold that health care providers who perform breast implant procedures are, in essence, providing a service. Although the breast implant procedure requires the use of a product, the implant, the health care provider is fundamentally and predominantly offering a service. The provider must have medical knowledge and skill to conduct the procedure. He must advise the patient of the medical consequences and must recommend to the patient the preferable type of procedure. The product may not be purchased independently of the service. One does not 'buy' a breast implant procedure in the same way as one would buy a product, such as a lawnmower. At its heart, the breast implant procedure is a service and not a product").

²⁰ *Constant v. Wyeth*, 352 F.Supp.2d 847, 853-54, n. 10 (M.D. Tenn. 2003).

²¹ TENN. COMP. R. & REGS. 1320-5-1-.26(1) (2008); see also *In Re: Memphis Kidney & Dialysis Services*, No. P-140905 T-A, at p. 2 (Tenn. State Bd. of Equalization, Admin. Judge for Shelby County, Tenn., Mar. 17, 2003) ("The testimony of Memphis Kidney & Dialysis Services' administrator establishes that the company is predominantly engaged in the delivery of medical services. Though billed separately for whatever drugs they may receive in connection with those services, Memphis Kidney & Dialysis Services' clients are essentially paying for dialysis treatment and related services.").

The MDL Tort Plaintiffs rest their argument as to the viability of the products claim on a singular provision in the Tennessee Code, § 29-28-103(b)(2), which excludes health care providers from the definition of sellers for breast implant products liability claims. They argue that this legislative *exclusion* is actually an *inclusion* of health care providers as sellers in all other contexts. This defies the title of the amendment²², the legislative history²³, and common sense²⁴. If the legislature intended to sanction suits against health care providers for strict liability in providing medical services, would it do so without saying it, and only by implication in an amendment to a statute of limitations provision? The SSC Defendants' position is that the legislature would not and did not do so.

* * * * *

Lastly, policy dictates a finding that a health care provider does not sell medication to the patient when using it incidental to treatment. To approve the Plaintiffs' cause of action would open the floodgates to strict product liability claims against health care providers for unknowingly using defective products and, further, would make health care providers the literal insurers of all they use, from bandages to prosthetics.

²² “[A]n Act to amend [29-28-103] relative to limitations of actions.” S.B. 196, 93rd Gen. Assemb., 1993 Sess. (Tenn.).

²³ Sponsor, Senator Harper: “[The bill] does not have to do with medical malpractice, that's not what this issue is about; it has to do with a product.” Statement of Sen. Harper, S. FINANCE, WAYS, & MEANS COMM., 14:01-14:10 (Apr. 27, 1993).

²⁴ See *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (whether claim is legally viable requires judicial application of common sense).

Regardless, even if the Plaintiffs are not constrained as a matter of law to bring these cases only under the THCLA, they cannot reasonably make a case that, on the facts pled and uncovered to date, the SSC Defendants were engaged in the business of selling medication when Dr. Lister injected it. No facts have developed in the underlying litigation to support the theory that SSC *sold* medication to patients as a merchant would sell a grocery item or piece of farm equipment, nor to support the allegation that SSC charged its patients specifically for the medication, as if they were selling it.

Again, applying common sense, does a doctor really “sell” a medication to a patient (as the hospital gift shop would sell a bottle of soda) when the patient does not pay for the medication and does not leave with the medication?

* * * * *

Admittedly, the MDL Court ruled that the MDL Plaintiffs’ product liability claim cleared the low hurdle of a motion to dismiss, particularly in the absence of an appellate court decision directly on point. The MDL Plaintiffs will, of course, continue to oppose the SSC Defendants’ efforts to have the product liability claim dismissed, whether it occurs in the MDL Court or this Court. However, when the claim is put to the test on the record developed in the MDL Court (or when the Tennessee Supreme Court considers the issue on certification), the SSC Defendants are confident in their position that the product liability claim is not legally viable. They maintain that position in the instant coverage action.

6. This question should probably ultimately be answered by the Tennessee Supreme Court.

The SSC Defendants should make one final point in explaining their position on the intersection of the MDL and this declaratory judgment action:

Respectfully, neither the Massachusetts District Court nor the Tennessee District Court can make a definitive, precedential ruling on whether, under Tennessee law, a plaintiff can sue a health care provider for “selling” medication when the medication is only used incidental to care of a patient. If a binding decision on this legal issue would decide a major component of the MDL cases and the primary issue in this coverage action, certification makes sense. Thus, for a definitive ruling, certification of the issue to the Tennessee Supreme Court is probably warranted.²⁵

7. Conclusion

To understand the SSC Defendants’ position on various issues at the intersection of the MDL and this coverage action, the above explanation is offered. On the precise and narrow issue before the Court now – whether to issue a stay of this coverage action – the Tennessee SSC Defendants take no formal position.

²⁵ Presently before the MDL Court is the question of where the MDL tort cases will be tried. The Tennessee SSC Defendants’ position is that they should be returned to Tennessee for trial after the completion of common discovery in the MDL. The MDL Plaintiffs disagree. Should the MDL Court keep the cases in Massachusetts for trial, there is a question as to whether the Massachusetts District Court can certify the issue to the Tennessee Supreme Court. See TENN. S. CT. R. 23 (“[t]he Supreme Court may, at its discretion, answer questions of law certified to it by the Supreme Court of the United States, a Court of Appeals of the United States, a District Court of the United States *in Tennessee*, or a United States Bankruptcy Court in Tennessee”) (emphasis added).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that Specialty Surgery Center, PLLC and Kenneth R. Lister, MD's Response to the Individual Tort Victims' Motion to Strike or Stay was served on the parties listed below through the Court's CM/ECF system on the 3rd day of September, 2015.

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/s/ Chris J. Tardio
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